



Presbia Achieves ISO Medical Device Quality Milestone

January 14, 2019

DUBLIN--(BUSINESS WIRE)--Jan. 14, 2019-- Presbia PLC (NASDAQ:LENS), an ophthalmic device company and leader in near-vision restoration, achieved a major milestone towards complying with the revised ISO (International Standards Organization) 13485:2016 by successfully completing the ISO 13485:2016 audit with no major findings. This was an essential step in recertifying under the ISO standard with annual surveillance audits for the next two years. The renewal of the company's CE Mark has been completed and is valid through 2022. Notified Body NSAI (National Standards Authority of Ireland) conducted the audit.

About ISO 13485 Transition from 2003 to 2016

In February 2016 the International Standards Organization (ISO) revised its medical device standard, ISO 13485:2003 to ISO 13485:2016, placing greater emphasis on medical device quality management systems (QMS) in all aspects of product lifecycle. The revised standard provided for a three-year transition period for medical device organizations to achieve compliance with ISO 13485:2016. The most significant changes between the original and revised standard include:

- Use of risk-based approaches in the context of the safety and performance of medical devices meeting regulatory requirements;
- Additional emphasis on complaint handling and reporting to regulatory authorities;
- Increased emphasis on documentation of corrective actions and preventive actions without undue delays;
- Increased linkage with regulatory requirements and related documentation;
- Increased focus on production of sterile medical devices and related sterile barriers in production; and
- Validation of software, production and supply-chain processes.

Bob Lundberg, Sr. Vice President, Regulatory and Quality of Presbia, said, "We are extremely pleased that we achieved recertification under ISO 13485 during the transitional period, and it further demonstrates our commitment to quality in all aspects of our business."

Forward-Looking Statements

This release contains "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Information provided and statements contained in this press release that are not purely historical are forward-looking statements. These statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will," "may," "should," or similar expressions. Such forward-looking statements only speak as of the date of this press release and Presbia assumes no obligation to update the information included in this press release. Statements made in this press release that are forward-looking in nature may involve risks and uncertainties, including, but not limited to, the factors listed under "Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2017, quarterly reports on Form 10-Q, and other reports that Presbia files with the SEC. Accordingly, readers are cautioned that any such forward-looking statements are not guarantees and are subject to certain risks, uncertainties and assumptions that are difficult to predict. Although Presbia believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. Unless otherwise required by law, Presbia also disclaims any obligation to update its view of any such risks or uncertainties or to announce publicly the result of any revisions to the forward-looking statements made in this press release.

About Presbia

Presbia PLC (NASDAQ:LENS) is an ophthalmic device company that has developed and is currently marketing the presbyopia-correcting Presbia Flexivue Microlens™, a miniature lens that is implanted in a corneal pocket created by a femtosecond laser. The Presbia Flexivue Microlens™ has received a CE mark for the European Economic Area, allowing the lens to be marketed in over 30 countries across Europe. A staged pivotal U.S. clinical trial for the Presbia Flexivue Microlens™ commenced in 2014. For more information please visit www.presbia.com

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